510(K) SUMMARY K992958

DEC - 2 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1. Submitter's Name: AViTA Corporation

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Contact: Mr. Nelson Lin / R&D Manager

2. Device Name :

Trade Name: **AViTA Scanéo IR Thermometer, Model no.: TS2x/TS3x series**

Common Name: IR Thermometer

Classification name thermometer, electronic, clinical

3. DEVICE CLASS The **AViTA Scanéo IR Thermometer (Model no. TS2x/TS3x series)** has been classified as

Regulatory Class: II

Panel: 80

Product Code: FLL

Regulation Number: 21CFR 880.2910

4. Predicate Device: The predicate device is the **AViTA TS8/TS9 series Scanéo IR Ear/Forehead Thermometer (K031503)** marketed by **AVITA CORPORATION**.

5. Intended Use: The **AViTA Sanéo IR Thermometer (Model no. TS2x/TS3x series)** is infrared thermometers intended for the intermittent measurement of human body temperature by people of all ages in the home.

6. Device Description: The **AViTA Scanéo TS2x/TS3x series IR Thermometer** is hand-held, non-sterile, reusable, battery operated device that can measure human body temperature.

The **AViTA TS2x series IR Ear Thermometer** measures

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human body temperature natural thermal infrared radiation emitted from the ear tympanic.

The **AViTA TS3x series IR Ear / Forehead Thermometer** can measure human body temperature in 2 ways:

(1) The temporal artery over forehead.

(2) Tympanic temperature via the human ear.

Operation is based on the measuring of the natural thermal infrared radiation emitted from the surface of the skin over the temporal artery or from the ear tympanic.

7. Performance Summary:

In terms of operating specification, Safety & EMC requirements, the device conforms to applicable standards included ASTM E1965-98(2003) , IEC 60601-1 and IEC 60601-1-2 requirements.

8. Conclusions:

The **AViTA Scanéo IR Thermometer (Model no. TS2x/TS3x series)** has the same intended use and similar technological characteristics as the **AViTA TS8/TS9 series Scanéo IR Ear/Forehead Thermometer (K031503)** marketed by **AVITA CORPORATION**. Moreover, bench testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, The **AViTA Scanéo IR Thermometer (Model no. TS2x/TS3x series)** is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

AViTA Corporation
C/O Ms. Jennifer Reich
Senior Consultant
Harvest Consulting Corporation
2904 North Boldt Drive
Flagstaff, Arizona 86001

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Re: K092958
Trade/Device Name: AViTA Sanéo IR Thermometer, Model no.: TS2x/TS3x Series
AViTA Corporation
Regulation Number: 21CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: October 29, 2009
Received: November 2, 2009

Dear Ms. Reich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ***K092958***

Device Name: **AViTA Sanéo IR Thermometer,**
Model no.: **TS2x/TS3x series**
AViTA Corporation

Indications For Use:

The **AViTA Sanéo IR Thermometer (Model no. TS2x/TS3x series)** is infrared thermometers intended for the intermittent measurement of human body temperature in people of all ages in the home.

Prescription Use _____ AND/OR Over-The-Counter Use V
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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